

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit - Unknown

In re

Patent Application of

Leslie A. Holladay

Serial No.: Unknown

Filed: December 10, 2001

Examiner: Unknown

“MODIFICATION OF POLYPEPTIDE
DRUGS TO INCREASE
ELECTROTRANSPORT FLUX”

CERTIFICATION UNDER 37 CFR 1.10

I, Leslie Rector, hereby certify that this correspondence is being deposited with the United States Postal Service in an envelope as “Express Mail Post Office to Addressee,” mailing Label Number EL832142055US, addressed to Assistant Commissioner for Patents, BOX PATENT APPLICATION, Washington, D.C. 20231

Leslie Rector
Signature

December 10, 2001

Date

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

Sir:

This application is a continuation of U.S. Patent Application Serial No. 08/466,610, filed under 37 CFR 1.53(b). Prior to examination on the merits, please amend the subject application as follows:

In the Specification:

Please amend the specification as follows:

On page 1, immediately before “**TECHNICAL FIELD**”, please add the following new paragraph and heading:

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Patent Application Serial No. 08/466,610, filed June 6, 1995.

Replace the first full paragraph on page 15 with the following:

Electrotransport delivery device 10 includes a donor electrode assembly 8 and a counter electrode assembly 9. Electrode assemblies 8 and 9 are electrically connected to an electrical power source 27, which is typically one or more low voltage batteries, and an optional control circuit 19. When the device 10 is placed on the skin or mucosal membrane of, e.g., a patient, the circuit between the electrodes is closed, and the power source begins to deliver current through the device and through the skin or mucosal membrane of the patient. The donor and counter electrode assemblies 8 and 9 normally include a strippable release liner (not shown in Figure 1) which is removed prior to application of electrode assemblies 8 and 9 to body surface 22.

Replace the first full paragraph on page 18 with the following:

Human parathyroid hormone (h-PTH) is a pharmaceutical polypeptide used to treat osteoporosis. An example of an analog of h-PTH is one in which the glutamine residue at position 29 is replaced by histidine to increase the net charge by about +1 at pH 5. Replacement of the glutamine residue at position 29 retains the approximate biological activity of the parent compound (SEQ ID NO:7).

In the Claims:

Please cancel claim 3.

Please add the following new claims 17 and 18:

17. (New) The method of claim 1, wherein the analog is provided in the form of an anionic donor reservoir formulation for delivering the analog through the body surface by electrotransport, the formulation having a pH in the range of about 3.5 to about 7.4.

18. (New) The method of claim 17, the formulation used for delivering the analog by electrotransport having a pH in the range of about 5 to about 7.4

Remarks:

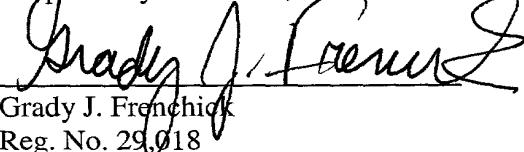
Consideration of the foregoing amendments and following remarks is respectfully requested.

The amendments to the specification, except for the addition of the "Cross Reference to Related Applications" paragraph, were also made in U.S. Patent Application Serial No. 08/466,610. Applicant respectfully submits that the amendments to the specification introduced herein adds no new matter to the subject patent application.

The amendment cancels claim 3 which was found to be subject to no sustainable rejections by the Board of Patent Appeals and Interferences (Paper No. 31, page 10) in parent U.S. Patent Application Serial No. 08/466,610. Claim 3 will now be passed to issue in the parent application. No new matter has been added to the subject application by way of the addition of new claims 17 and 18. Claims 1-16 were the subject of the restriction requirement on 12/14/95 in U.S. Patent Application Serial No. 08/466,610 (Paper No. 4). Claims 5-16 were withdrawn from consideration and not further prosecuted. Claims 17 and 18 also were added during prosecution of the parent application (Amendment dated 6/13/96). Rejection of claims 1, 2, 4, 17 and 18 was sustained by the Board.

Applicant respectfully submits that the remaining claims in the present application are in condition for allowance. A favorable action thereon is, therefore, respectfully requested. Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the number listed below.

Respectfully submitted,


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"Version with markings to show changes made"

The changes made to the specification are shown by brackets [for deleted matter], and underlining for added matter.

In the specification, page 15, first full paragraph.

Electrotransport delivery device 10 includes a donor electrode assembly 8 and a counter electrode assembly 9. Electrode assemblies 8 and 9 are electrically connected to an electrical power source 27, which is typically one or more low voltage batteries, and an optional control circuit 19 [which is described in more detail hereinafter]. When the device 10 is placed on the skin or mucosal membrane of, e.g., a patient, the circuit between the electrodes is closed, and the power source begins to deliver current through the device and through the skin or mucosal membrane of the patient. The donor and counter electrode assemblies 8 and 9 normally include a strippable release liner (not shown in Figure 1) which is removed prior to application of electrode assemblies 8 and 9 to body surface 22.

In the specification, page 18, first full paragraph.

Human parathyroid hormone (h-PTH) is a pharmaceutical polypeptide used to treat osteoporosis. An example of an analog of h-PTH is one in which the glutamine residue at position 29 is replaced by histidine to increase the net charge by about +1 at pH 5. Replacement of the glutamine residue at position 29[.6] retains the approximate biological activity of the parent compound (SEQ ID NO:7).